



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0787]

Draft Guidance for Industry and Food and Drug Administration Staff; Investigational Device Exemptions for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human Studies; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice that appeared in the Federal Register of Thursday, November, 10, 2011 (76 FR 70150). In the notice, FDA requested comments on the draft guidance that addresses the approaches FDA intends to facilitate early feasibility studies of medical devices, using appropriate risk mitigation strategies, under the investigational device exemption (IDE) requirements. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments and information by March 9, 2012.

ADDRESSES: Submit electronic comments on the draft guidance to

<http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Dorothy Abel,
Center for Devices and Radiological Health,
Food and Drug Administration,
10903 New Hampshire Ave.,
Bldg. 66, rm. 1204,
Silver Spring, MD 20993-0002,
301-796-6366.

I. Background

In the Federal Register of November 10, 2011 (76 FR 70150), FDA published a notice announcing the availability of the draft guidance entitled “Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies” and the opening of a public docket to receive comments on the key principles unique to the justification for, and design of, early feasibility studies, as well as outlines the general principles for preparing and reviewing early feasibility study IDE applications that are discussed in the guidance. Interested persons were invited to submit comments by February 8, 2012. At this time, the Agency is extending the comment period until March 9, 2012, to continue to receive public comments. Comments submitted to the docket will enhance the development and review of IDE applications for early feasibility studies of significant risk for the industry and the Center for Devices and Radiological Health.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only

necessary to submit one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in the brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-33142 Filed 12/23/2011 at 8:45 am; Publication Date: 12/27/2011]